

BAKER BOTTS LLP.Attorney Docket No.: A32011-A-PCT-USA (072448.0313)
PATENT**REMARKS**

This paper is being filed in response to the non-final Office Action dated May 6, 2004. Applicants have included with this Reply a Declaration of Dr. Antonio A. Garcia pursuant to 37 C.F.R. § 1.132 ("Rule 132 Declaration"). Applicants respectfully assert that this Reply and Rule 132 Declaration are fully responsive to each of the objections raised in the outstanding Office Action.

Claims 1-9 are pending. Claims 1 and 5 are amended herein and contain no new matter. Support for the amendments can be found in the specification, claims and drawings as originally filed.

Claims 1 and 2 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 5,552,086 to Siiman et al. ("Siiman").

Claims 1-4 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Siiman in view of U.S. Patent No. 5,232,829 to Longiaru et al. ("Longiaru").

Further, Claims 1-9 are rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. Alternatively, Claims 1-9 are rejected under 35 U.S.C. § 103(a) as allegedly obvious over Garcia et al., *Reactive Polymers*, 1994, 23(2-3):249-259 ("Garcia") in view of U.S. Patent No. 4,945,057 to Temeyer ("Temeyer").

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PATENT**Rejections Under 35 U.S.C. § 102(b)**

The Examiner has rejected Claims 1 and 2 as allegedly anticipated by Siiman. Applicants respectfully disagree with the Examiner's conclusion. Nevertheless, Applicants have amended Claim 1 to require that the silver ions be directly immobilized on the plate. This amendment makes clear that the invention by Siiman is not an anticipatory reference to this invention since the silver ions taught by Siiman - quite unlike those of the claimed invention - are not complexed in a manner that makes them available, in turn, for complexing with the sulfur atom in biotinylated antibodies.

Thus, Siiman does not teach every element of Claims 1 and 2, and therefore cannot anticipate the presently claimed invention. This conclusion is supported by the attached Rule 132 Declaration of Dr. Garcia. Accordingly, Applicants respectfully submit that the rejections of the claims under 35 U.S.C. § 102(b) should be withdrawn.

Rejections Under 35 U.S.C. § 103(a)

The rejections of Claims 1-4 under 35 U.S.C. § 103(a) as allegedly obvious over Siiman in view of Longiaru have been maintained. The May 6, 2004 Office Action contends that "the functional limitation of the plate (i.e., the plate is substantially transparent) does not distinguish the presently claimed apparatus because Siiman et al. and Longiaru et al. meets all the structural limitation of the claimed apparatus." In order to more clearly identify the structure being claimed, Applicants have amended Claim 1 to require a "substantially transparent support."

The Office Action also contends that one of ordinary skill in the art would have had an expectation of success to make the asserted combination. Applicants respectfully

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disagree. The standard for obviousness requires that the cited art teach or suggest each and every limitation of the claims. Further, the Court of Appeals for the Federal Circuit has held that there can be no suggestion or motivation to modify a reference if doing so would render the prior art device inoperative for its intended purpose. *See e.g. In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984).

In our Reply to the Office Action dated October 16, 2003, Applicants argued that the asserted combination would render both the particles of Siiman and the plates of Longiaru inoperative. This argument does not appear to have been addressed by the Examiner in the May 6, 2004 Office Action. Applicants respectfully request consideration of this argument because the metal-coated colloidal particles of Siiman are used in flow cytometry methods, which take advantage of the particle's light-scattering properties, therefore the application of the particles of Siiman to the plates of Longiaru would render the Siiman particles unfit for their intended purpose, *i.e.* immobilized particles cannot be used in flow cytometry applications.

Reciprocally, incorporating the light-scattering particles of Siiman into the plates of Longiaru would render the plates unsuitable for hybridization capture of PCR-amplified DNA for at least three reasons. First, given the high affinity of biotin for silver, introducing silver to the plates of Longiaru would lead to unacceptably high levels of non-specific binding of PCR-amplified DNA labeled with biotin. In fact, it would be readily apparent to one of ordinary skill in the art that it would be nearly impossible to detect specific binding interactions under such conditions. Second, the light-scattering property of the particles of Siiman would interfere with the colorimetric detection methods taught by Longiaru. Third, passive binding of the Longiaru capture probe may be reduced or blocked if the plates are first coated with the particles of

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Siiman. Consequently, no suggestion or motivation to combine these references can be inferred. Indeed, the references teach away from any such combination. Thus, Siiman over Longiaru does not render Claims 1-4 obvious.

The Examiner also rejected Claims 1-9 under 35 U.S.C. § 103(a) as allegedly obvious over Garcia in view of Temeyer. Because the Garcia reference discloses use of a bioassay for amino acids only, it should not serve as a 103(a) reference here. The present invention discloses a bioassay capable of detecting antibodies and antigens.

The proper standard for whether the Garcia reference should be applied here in an obviousness analysis is whether there would be a reasonable expectation of success in combining the asserted references. *See e.g., In re Antonie*, 559 F.2d 618, 620 (C.C.P.A. 1977) (obvious to try is not the standard of 35 U.S.C. § 103(a)); *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986) (“[T]he board’s decision was premised on an impermissible obvious to try standard.”). The Office Action does not explain why a person of ordinary skill in the art would have reasonably expected success in making and/or using the claimed invention. As indicated in the attached Rule 132 Declaration, the specific location of biotin on antibodies and their site-specific binding to antigens cannot be accurately predicted with very simple molecules such as amino acids. Therefore, Applicants assert that no reasonable expectation of success existed at the time of the present invention.

Accordingly, Applicants respectfully submit that the rejections of the claims under 35 U.S.C. § 103(a) should be withdrawn.

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PATENT**Rejections Under 35 U.S.C. § 112, Second Paragraph**

The Examiner has rejected Claims 1-9 under 35 U.S.C. § 112, ¶ 2 as allegedly indefinite for reciting the phrase "substantially transparent." However, using such terminology does not necessarily render a claim indefinite. *See e.g., Andrew Corp. v. Gabriel Electronics, Inc.*, 847 F.2d 819 (Fed. Cir. 1988); MPEP § 2173.05(b). *Application of Swinehart*, 439 F.2d 214 (C.C.P.A. 1971), is instructive:

The record before us establishes that prior art compositions are substantially opaque to infrared rays. Appellants have produced a composition which is substantially transparent to such rays ... It is true that the figures reproduced in the specification indicate that the degree of transparency varies depending on such factors as the conditions employed ... and the particular wavelength of the radiation transmitted. However, in all cases a substantial amount of infrared radiation is transmitted. We do not read appellants' disclosure as suggesting that only certain degrees of transparency to infrared are comprehended within the teaching there given. It follows that when appellants' claim is read in light of that disclosure the limits it purports to define are made sufficiently clear.

Id. at 214. In drawing an analogy to that case, Applicants assert that when read in light of the specification, the term "substantially transparent" is definite such that one of ordinary skill in the art would understand the meaning of the term as used in the claims. The Federal Circuit has recently reiterated that: "a claim is not indefinite merely because its scope is not ascertainable from the face of the claims ... rather, a claim is indefinite under § 112, ¶ 2 if it is 'insolubly ambiguous and no narrowing construction can be properly adopted'." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1342 (Fed. Cir. 2003) (internal citations omitted).

Based on the foregoing, Applicants respectfully request that the rejection based on 35 U.S.C. § 112, ¶ 2 be withdrawn.

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PATENT**Conclusion**

Applicants respectfully request reconsideration of the outstanding rejections, and entry of the above amendments and remarks into the file history of the above-identified application. Applicants believe that the above amendments and remarks place the claims in condition for allowance, and accordingly, respectfully request withdrawal of the outstanding rejections. An early allowance is earnestly sought.

Respectfully submitted,

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